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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

December 17, 2004

Ref: 2005-DAL-WL-09

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David Boudreaux, R.Ph./President
Red River Pharmacy Services, Inc.
1327 College Drive
Texarkana, Texas 65503

Dear Mr. Boudreaux:

An inspection of your veterinary drug compounding facility, located at the above address, conducted by investigators of the Food and Drug Administration (FDA) from this office, between the dates of June 22 and 25, 2004, disclosed significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigators were accompanied by Mr. Christopher Schuttler, Compliance Inspector, with the Texas State Board of Pharmacy (TSBP).

Our investigation revealed that Red River Pharmacy Services, Inc. has compounded and distributed veterinary drugs, including Apomorphine, Domperidone, Chloramphenicol, and Nitrofurazone, using bulk active pharmaceutical ingredients (APIs). The veterinary drugs you are compounding are unsafe within the meaning of section 512 of the Act (21 U.S.C. § 360b) since they are not the subject of approved New Animal Drug Applications. As such, they are adulterated under section 501(a)(5) of the Act (21 U.S.C. § 351(a)(5)). Sections 512(a)(4) and (5) of the Act (21 U.S.C. 360b(a)(4) and (5), and their implementing regulations, allow some extralabel use of approved animal and human drugs, including compounding from such approved animal and human drugs. These provisions, however, apply only to approved drugs and do not permit compounding from bulk APIs (see Title 21, Code of Federal Regulations (CFR), 530.13(a)).

FDA's policy regarding the compounding of drugs for use in animals is articulated in Compliance Policy Guide, Section 608.400, issued July 2003. As stated in this policy, FDA is greatly concerned about veterinarians and pharmacies that manufacture and

distribute unapproved new animal drugs in a manner that is clearly outside the bounds of traditional pharmacy practice and that violates the Act.

One of our concerns is that you are not compounding for individual patients, but are compounding for third parties who resell to individual patients. A significant number of your compounded veterinary drugs appear to be compounded outside the context of a valid veterinarian-client-patient relationship (VCPR) for administration by an end user. Instead, they appear to be sales to veterinarians for use as office stock in their professional practice and/or for subsequent general distribution. For example, only 50% of your product goes directly to the end user. In addition, your prescription drug labeling for clinic use does not indicate species, dosage frequency, or duration of treatment.

Another concern is that you are compounding drugs for use when an approved drug, in the available dosage form and concentration, would appropriately treat the animal. For example, some of your compounded prescription veterinary drugs, such as Nitrofurazone .2% topical solution, are duplicates of FDA approved animal drug products available on the market. Others have only slightly different dosages and/or concentrations than FDA approved animals drugs, such as Praziquantel 35 mg capsules where Praziquantel 34 mg capsules are approved and available; these differences appear to be clinically insignificant.

A third concern is that the drugs being compounded could be used in food producing animals and, therefore, could result in unsafe drug residues in edible tissues. For example, the prescriptions you receive and the labeling you generate often do not specify the target animal species. Moreover, at least two of the drugs being compounded, nitrofurazone and diethylstilbestrol, are not permitted for extralabel use in food producing animals because they present a risk to public health.

Our inspectional findings were listed on a Form FDA 483, Inspectional Observations, which was issued and discussed with you at the end of the inspection. We acknowledge receipt of your response to the FDA-483 dated June 25, 2004. We consider your response to be inadequate because it does not completely address all the observations conveyed to you on the FDA-483 in an appropriate manner. It is recommended that specific details be provided in your response, such as what specific procedures have or will be implemented to eliminate the compounding of duplicates of approved veterinary or human drugs, and what specific procedures will be initiated to provide assurance that the prescribed veterinary drug product's labeling includes sufficient information.

The above is not intended to be an all-inclusive list of violations by your firm. It is your responsibility to ensure that your firm's operations and products are in compliance with the law and applicable regulations.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

Please notify this office within fifteen (15) working days of receiving this letter, of the further specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time period within which the corrections will be completed. You may address your reply to Edwin Ramos, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

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